UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL 2804
	Case No. 17-md-2804
This document relates to:	Hon. Dan Aaron Polster
Track One Cases	

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR PARTIAL SUMMARY ADJUDICATION OF DEFENDANTS' DUTIES UNDER THE CONTROLLED SUBSTANCES ACT

INTRODUCTION

There presently exists a dispute amongst the parties on whether the federal Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801 *et seq*. and its implementing regulations, 21 C.F.R. 1301 *et seq.*, mandate that registrants halt, and not ship, suspicious orders of prescription opioids unless and until they have determined that diversion is not likely. Plaintiffs have asserted several claims for which the Defendants' compliance with the CSA is relevant, including claims under the federal Racketeer-Influenced and Corrupt Organizations ("RICO") Act, Ohio's parallel RICO statute, and Ohio's absolute public nuisance law. While it is clear that Manufacturer and Distributor Defendants are subject to regulation under the CSA, the legal dispute over the scope of those requirements must be resolved before the Court can determine factually whether any of the Defendants are in compliance. Resolution of this legal issue will also substantially advance resolution of the claims asserted by litigants from across the country in both federal and state courts. Through this motion, Plaintiffs seek summary adjudication of this legal question, which will streamline and focus the presentation of evidence at trial.

The CSA requires registrants to maintain "effective controls against diversion." 21 U.S.C. § 823(a)(1), (b)(1). Pursuant to regulations adopted by the federal Drug Enforcement Administration ("DEA"), the agency charged with administration of the CSA, the maintenance of such controls requires registrants to design and operate a system for identifying and reporting suspicious orders. *See* 21 C.F.R. § 1301.71(a). The dispute at issue on this motion concerns the further duty to refrain from shipping suspicious orders until the registrant can determine, through investigation, that the order is not likely to be diverted. As described below, the DEA has construed the CSA to impose this requirement because a registrant's controls against diversion will not be effective if suspicious orders are merely identified and reported, but are nonetheless shipped before it can be determined that they are unlikely to be diverted. *See Masters Pharmaceutical, Inc. v. Drug Enforcement Administration,* 861 F.3d 206, 212-213 (D.C. Cir. 2017); *Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 FR 36487-01, 36500, 2007 WL 1886484 (DEA July 3, 2007). Congress has recently ratified this construction. *See* Public Law 115-271, § 3272. Special Master Cohen has recognized this interpretation. *In re National Prescription Opiate Litigation*, MDL2804, Discovery Ruling No. 12 [Doc. 1174] (December 9, 2018). Because the DEA's construction as ratified by Congress is correct, this Court should rule as a matter of law that registrants are required to identify, report, and stop suspicious orders, pending investigation.

LEGAL STANDARD

Rule 56 provides that "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Rule 56 permits a party to move for summary judgment on a claim or defense or on a "part of [a] claim or defense." Fed. R. Civ. P. 56(a). The rule thus "make[s] clear at the beginning that summary judgment may be requested not only as to an entire case but also as to a claim, defense, or part of a claim or defense." Fed. R. Civ. P. 56, Advisory Committee Notes, subdivision (a) (2010). "Statutory interpretation is a matter of law appropriate for resolution on

summary judgment." *Thomas v. Metro. Life Ins. Co.*, 631 F.3d 1153, 1160 (10th Cir. 2011); *see also Walsh v. United States*, 31 F.3d 696, 698 (8th Cir. 1994)(where an unresolved issue is "primarily legal rather than factual, summary judgment is particularly appropriate."); *Brown v. Smith*, 827 F.3d 609, 613 (7th Cir. 2016) (a "question of law" suitable for summary adjudication "typically concerns the meaning of a statutory or constitutional provision, regulation, or common law doctrine").

ARGUMENT

THE CSA DUTY TO "MAINTAIN EFFECTIVE CONTROLS AGAINST DIVERSION" REQUIRES DEFENDANTS TO IDENTIFY AND REPORT SUSPICIOUS ORDERS AND TO HALT SHIPMENTS OF SUCH ORDERS PENDING INVESTIGATION

The CSA sets forth as a primary factor in the grant of a registration to manufacture or distribute controlled substances the "maintenance of effective controls against diversion . . . into other than legitimate . . . channels . . . ." 21 U.S.C.A. § 823(a)(1), (b)(1). This duty has remained substantially unchanged since the enactment of the CSA in 1970. This duty is further codified by the DEA at 21 C.F.R. § 1301.71(a), which provides that "[a]ll applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances." This requirement has remained substantially unchanged since its adoption by the DEA in 1971. 36 Fed. Reg. 4928 (1971); 36 Fed. Reg. 7776 (1971).

The duty to maintain effective controls against diversion is not merely a technical requirement. The regulatory scheme established by the CSA does not rely on the DEA to police shipments of controlled substances in the first instance, but rather enlists registrants and requires them to assume that task, in exchange for the privilege of dealing in the drugs. *See Southwood Pharmaceutical*, 72 FR 36487-01, 36504, 2007 WL 1886484 (the DEA cannot all by itself "protect the American people from [the] extraordinary threat to public health and safety" posed by prescription narcotics; it "must rely on registrants to fulfill their obligation under the Act to ensure that they do not supply controlled substances to entities which act as pushers."). Moreover, the legislative history of the CSA shows that

one of the fundamental purposes of the statute is to protect society from the dangers that controlled substances pose to the safety of communities. H.R. Rep. 91-1444, 4574, 4601-2 (1970). As the DEA noted in revoking the registration of a distributor in *Southwood Pharmaceuticals*, "[r]espondent's distribution of 44 million dosage units of hydrocodone which were likely diverted caused extraordinary harm to the public health and safety." 72 FR 36487-01, 36503, 2007 WL 1886484. Indeed, the DEA characterized the recipients of the suspicious orders as "drug pushers operating under the patina of legitimate authority" and found that "[c]utting off the supply sources of these pushers is of critical importance in protecting the American people from this extraordinary threat to public health and safety." *Id.* at 36504.

The DEA has construed the CSA to require registrants to design and operate a system to identify suspicious orders of controlled substances (the "identification duty"); to report to the DEA suspicious orders when discovered (the "reporting duty"); and to decline to ship an order identified as suspicious unless and until, through due diligence, the registrant is able to determine that the order is not likely to be diverted into illegal channels (the "no-shipping duty"). *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration,* 861 F.3d 206, 212-213 (D.C. Cir. 2017);[1] *see also Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 FR 36487-01, 36500, 2007 WL 1886484 (DEA July 3, 2007). The first two of these duties, the identification and reporting requirements, are explicitly set forth at 21 C.F.R. § 1301.74, which provides that a registrant "shall design and operate a system to disclose to the registrant suspicious orders of controlled substances" and that the registrant "shall inform the Field Division Office of the Administration in his area of suspicious orders *when discovered by the registrant*." (Emphasis added.) The regulation defines suspicious orders to include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

[1] In *Masters Pharmaceutical*, the court described this as a "shipping duty." Because the duty as described by the *Masters Pharmaceutical* court and by the DEA clearly requires registrants to refrain from shipping, Plaintiffs here refer to it as the "no-shipping duty" in the interest of clarity,

Id. Defendants do not, in general, dispute that they are subject to the identification and reporting duties.

Although at least some of the Defendants dispute the DEA's authority to do so, the DEA has long recognized that the CSA imposes a no-shipping duty – that is, a duty to *not to ship* suspicious orders until they have been cleared through investigation. *See Masters Pharmaceutical,* 861 F.3d at 212-13 ("Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order."); *Southwood Pharmaceuticals,* FR 36487-01, 36500, 2007 WL 1886484; *see also* Exhibit A, DEA Rule 30(b)(6) Depo. (Prevoznik), Vol. 2, p. 771 (April 18, 2019) ("Q.: Does the DEA take the position that a registrant of controlled substances has a duty to block shipments of suspicious orders? A: Yes.").[2] As explained by the DEA in *Southwood Pharmaceuticals,* the no-shipping duty follows directly from the statutory requirement that a registrant maintain effective controls against diversion. In *Southwood Pharmaceuticals,* the DEA revoked the registration of a distributor based primarily on the failure to maintain such controls. The DEA found that not only had Southwood failed to report suspicious orders, but also that it had failed to perform proper due diligence with respect to its customers, and that it had continued to ship to certain customers, even though the orders it shipped met the criteria to be considered "suspicious." 72 FR 36487-01, 36498-99. Indeed, the DEA found it "especially appalling" that, in light of the information available to it indicating that certain pharmacies to which it was shipping hydrocodone were engaging in diversion, Southwood "did not immediately stop distributing hydrocodone to any of the pharmacies." *Id.* at 36500. The DEA noted "the threat to public safety posed by the diversion of controlled substances" and revoked Southwood's license, effective immediately, finding that "continued registration constituted an imminent danger to public health and safety." *Id.* at 26504.

[2] The DEA produced Thomas Prevosnik as a Rule 30(b)(6) witness in these proceedings. Mr. Prevosnik's testimony thus represents the official position of the DEA.

Thus, Southwood's violation of the no-shipping requirement was one of the primary reasons its registration was revoked.

If the Defendants were ever in any doubt about the requirement that they stop shipment of suspicious orders, the DEA unequivocally removed that doubt in letters it sent to opioid distributors in 2006 and 2007. In a September 26, 2006 letter, the DEA reminded distributors that in addition to an obligation to report suspicious orders, they had a "statutory responsibility to exercise due diligence to avoid *filling* suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." *See* Exhibit B (emphasis added). (Notably, this letter was sent approximately ten months before the administrative decision revoking Southwood Pharmaceuticals's registration.) In December, 2007, the DEA once again reminded distributors that

> their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders *prior to completing a sale* to determine whether the controlled substances are likely to be diverted from legitimate channels."

See Exhibit C (emphasis added). The letter concluded with the warning that "registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion." *Id.*

As the DEA letters make clear, and as explained in *Southwood Pharmaceutical*, the no-shipping duty is nothing more than an implementation of the basic duty to "maintain effective controls against diversion." *See* FR 36487-01, 36498-502, 2007 WL 1886484. Put another way, there can be no "effective controls against diversion" if a registrant is permitted to ship opioid orders it knows or should know bear the indicia of likely diversion. Thus, the no-shipping duty is not a later addition to the CSA or the regulations, but part and parcel of the original enactment. It is an "interpretive rule," which, rather than creating new duties, "simply states what the administrative agency thinks the statute means, and only reminds affected parties of existing duties. . . ." *Tennessee Hosp. Ass'n v. Azar*, 908 F.3d

1029, 1042 (6th Cir. 2018). Indeed, the *Southwood Pharmaceutical* proceedings confirm this is so: if the duty had not already existed, Southwood would not have lost its registration for failing to comply with it.

DEA's construction is plainly correct that *effective* control against diversion cannot be maintained if suspicious orders are shipped without investigation. Suspicious orders are, by definition, orders that that bear some indicia of diversion activity, including unusual size, unusual patterns, and/or unusual frequency. 21 C.F.R. § 1301.74(b). They are orders that raise sufficient concerns about diversion that they must be reported to the DEA. *Id.*; *see also* Exhibit C ("The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders *when discovered* by the registrant.") (emphasis in original). It is therefore reasonable to conclude that shipping suspicious orders without further investigation will not be an effective means to prevent diversion. Indeed, the construction recognizes that the registrants are partners with the DEA in the prevention of diversion, and that reliance on the DEA alone to prevent diversion using the information reported to it will not be a system of effective controls. *See Southwood Pharmaceutical*, 72 FR 36487-01, 36504, 2007 WL 1886484.

That this construction of the CSA is correct was recently confirmed by Congress. On October 24, 2018, Congress enacted Public Law 115-271, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the "SUPPORT Act"). Among other provisions, the SUPPORT Act amended 21 U.S.C. § 827 so as to provide manufacturers and distributors with access to data from the Automated Reports and Consolidated Orders System ("ARCOS"). *See* 21 U.S.C. § 827(f). As the SUPPORT Act explains, "The purpose of this chapter is to provide drug manufacturers and distributors with access to anonymized information through the Automated Reports and Consolidated Orders System to help drug manufacturers and distributors identify, report, *and stop* suspicious orders of opioids and reduce diversion rates." PL 115-271, § 3272

(emphasis added). But the SUPPORT Act goes even further – the statute also provides a "Rule of Construction" explaining that "Nothing in this chapter should be construed to absolve a drug manufacturer, drug distributor, or other Drug Enforcement Administration registrant from the responsibility of the manufacturer, distributor, or other registrant to— (1) identify, *stop*, and report suspicious orders; or (2) maintain effective controls against diversion. . . ." *Id.* (emphasis added).

Congress thus made crystal clear that the purpose of this particular provision of the SUPPORT Act is to give registrants additional tools – in the form of ARCOS data – to carry out their CSA duties, *including the duty to stop shipments*, and that the provision of these tools (or any previous lack of access to them) does not in any way absolve registrants of their statutory and regulatory duties, *including the existing duty to stop suspicious orders.*

In so doing, it is clear that Congress was aware of the DEA's construction of "effective controls against diversion" and intended to ratify it. "Subsequent legislation declaring the intent of an earlier statute is entitled to great weight in statutory construction." *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 380–81, (1969); *accord Salmi v. Sec'y of Health & Human Servs.*, 774 F.2d 685, 689–90 (6th Cir. 1985); *In re Buren*, 725 F.2d 1080, 1087 (6th Cir. 1984). It is also significant that, in ratifying the DEA's construction of the CSA, Congress did not amend the CSA to impose more explicitly the no-shipping requirement. This court can reasonably infer that Congress did not expressly impose this duty because it understood that the duty *already* existed under the CSA, and that it was necessary only to make clear how the provisions of the SUPPORT Act might affect that duty. *See Heckler v. Turner*, 470 U.S. 184, 211 (1985) (clarification in subsequent legislation of existing statute not only "leaves no doubt as to the prospective interpretation of the statute, but it carries in addition considerable retrospective weight").

DEA's construction of the CSA and the regulations would, even without the confirmatory legislation, be entitled to substantial deference. *See Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*,

467 U.S. 837, 843-44 (1984) ("considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer"); *Alliance for Community Media v. F.C.C.*, 529 F.3d 763, 776 (6th Cir. 2008); *Pension Ben. Guar. Corp. v. Bendix Comm. Veh. Sys's, LLC*, No. 1:11 CV 1961, 2012 WL 629928, at *6 (N.D. Ohio Feb. 24, 2012). Congress left it to the DEA to determine what constitutes "effective control against diversion" and DEA has made a reasonable determination of what is required. Moreover, as the Sixth Circuit has explained, in assessing an agency construction, the court "need not conclude that the agency construction was the only one it permissibly could have adopted to uphold the construction, or even the reading [it] would have reached. . . ." *Alliance for Community Media,* 529 F.3d at 778. Rather, it is sufficient that the interpretation is a reasonable one. *Id.*; *see also Hernandez,* 914 F.3d at 433 ("the question for the court is whether the agency's answer is based on a permissible construction of the statute"). Indeed, a court "may not disturb an agency rule unless it is arbitrary or capricious in substance, or manifestly contrary to the statute." *Zurich Am. Ins. Grp. v. Duncan on behalf of Duncan*, 889 F.3d 293, 302 (6th Cir. 2018); *see also Turfah v. United States Citizenship & Immigration Servs.*, 845 F.3d 668, 673 (6th Cir. 2017) (court "must defer" to agency interpretation if it is reasonable).

Congress's 2018 recognition of the no-shipping requirement adds even greater force to the deference that would usually be accorded to an agency interpretation, and leaves no room for doubt that, in order to carry out the statutory mandate to "maintain effective controls against diversion," a registrant may not ship suspicious orders that have not been cleared through investigation. It must, instead, block those orders until it can determine that diversion is unlikely.

CONCLUSION

For the foregoing reasons, this Court should rule that the CSAS imposes an obligation to maintain effective controls against diversion, and that in order to meet this obligation, registrants must design and operate a system to identify suspicious orders; must report suspicious order to the DEA when they are discovered; and must stop shipment of suspicious orders pending investigation.

Dated: June 25, 2019

Respectfully submitted,

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